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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of	)	Group Art Unit 1614
YUSUF ALI, et al.	)	Vickie Kim, Examiner
Serial No. 10/068,633	)	Confirmation No. 8088
Filed 02/05/2002	)	
For SKIN SANITIZING ANTIMICROBIAL ALCOHOLIC COMPOSITIONS	)	

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Melinda A. Miller

Melinda Miller, Sec'y to Rodney L. Skoglund

TRANSMITTAL SHEET

Enclosed are the following documents:

Appeal Brief

Amendment

Check in the Amount of $330.00

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The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. 18-0987. If a withdrawal is required from Deposit Account No. 18-0987, the undersigned attorney respectfully requests that the Commissioner of Patents and Trademarks cite Attorney Docket Number GOJ.P.78 for billing purposes.

Respectfully submitted,

Rodney L. Skoglund

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Attorney Docket No: GOJ.P.78

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APPLICANT'S BRIEF PURSUANT TO 37 C.F.R. 1.192

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal to the Board of Patent Appeals from the final rejection in the Office Action dated December 22, 2003. The Notice of Appeal was mailed on June 24, 2004. The present appeal is of Claims 1, 3, 5-9, 12 and 25, not Claims 1-10, 12 and 25 as originally set forth in the Notice of Appeal. The appeal brief has been submitted herewith in triplicate.

I. REAL PARTY AND INTEREST

The owner of the present application is GOJO Industries, Inc. The assignment was filed in the assignment division of the United States Patent and Trademark Office on April 17, 2002, and was recorded in the records of the United States Patent and Trademark Office at Reel/Frame 012844/0661 on April 25, 2002. GOJO Industries, Inc. is organized under the laws of the state of Ohio, U.S.A. and has a place of business at One GOJO Plaza, Suite 500, Akron, Ohio 44309.

II. RELATED APPEALS AND INTERFERENCES

Appellant's representatives and Assignee are not aware of any related appeals or interferences which would be directly affected by, or have a bearing on the Court's decision in the present pending appeal.

III. STATUS OF CLAIMS

The present application was filed on February 5, 2002 with claims 1-25, inclusive. An Office Action mailed on May 5, 2003 required the election of either the invention recited in claims 1-12 and 25 directed toward a composition or claims 13-24 directed toward a method. Applicant/Appellant elected the composition claims 1-12 and 25. Such a response to the Office Action, together with amendments made in light of the cited prior art, was made on August 5, 2003. Claims 1-10, 12 and 25 remain pending in the application at this time.

A final Action was mailed on December 22, 2003 rejecting those pending claims. A Response to the final Action was filed on April 20, 2004 again amending claims 1 and 25. In addition, claims 2, 4, and 10 were cancelled without prejudice or disclaimer. An Advisory Action was mailed on June 16, 2004 maintaining the prior rejections of the claims except for the withdrawal of a 112 new matter rejection. The Advisory Action did not indicate whether the proposed amendments would be entered for purposes of appeal. Consequently, following a telephone interview with the U.S. Patent Examiner on July 2, 2004, the Examiner submitted a Supplemental Advisory Action indicating that the proposed amendments would be entered for purposes of appeal. Therefore, claims 1, 3, 5-9, 12 and 25 remain pending in the present application and constitute the claims on appeal. Claims 1, 3, 5-9, 12 and 25 appear in Appendix 1 of Section IX, which is attached hereto.

IV. STATUS OF AMENDMENT

All amendments presented to date have been entered. Applicants have submitted contemporaneously herewith another amendment to incorporate matter which the Examiner asserted was essential subject matter incorporated by reference into the

specification and claims 1 and 6 of the subject application. A decision as to entry of these amendments remains pending.

V. SUMMARY OF THE INVENTION

The present invention relates to an antimicrobial sanitizing composition comprising at least 60% alcohol, a thickener containing a thickening agent, and a neutralizing agent containing a neutralizer. The alcohol is selected from the group consisting of methanol, ethanol, propanol, isopropanol, butanol, isobutanol, and tertiary butanol. The thickening agent is a carbomer polymer. The neutralizer is one designated by the FDA as of February 5, 2002, as a direct food substance that is Generally Recognized As Safe (GRAS) or an amino acid permitted for direct addition to food for human consumption. The composition also has other characteristics, including a density of at least 0.8 g/ml and a viscosity of from about 1,000 to about 65,000 centipoise at 70°F. Also, the composition is not a mousse.

The inventiveness of the present application lies in the fact that for high alcoholic compositions, only certain limited neutralizers can be used with carbomer thickening polymers. In fact, heretofore, it was thought that triethanolamine, sodium hydroxide, monoethanolamine, and dimethylstearylamine and all of the other above GRAS neutralizers were not compatible as neutralizing agents for compositions containing greater than 60% alcohol because they do not cause the thickening agent to gel the composition to the desired viscosity. The present invention has found that by controlling the pH and the order in which the ingredients of the hand sanitizing compositions are combined, sodium hydroxide as well as the other neutralizing agents identified above can be effective neutralizing agents for compositions containing high amounts of alcohol. Clearly, no prior antimicrobial skin cleansing compositions comprise such a high amount of aliphatic alcohol, a thickening agent and the stated neutralizers.

VI. ISSUES

1. Are claims 1 and 6 rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention?

2. Are claims 1, 3, 5-7, 9, 12 and 25 unpatentable under 35 U.S.C. §102(b) as being anticipated by Samour et al. U.S. Patent No. 5,976,566?

3. Are claims 1, 5-7, 9, 12 and 25 unpatentable under 35 U.S.C. §102(b) as being anticipated by McKenzie et al. U.S. Patent No. 5,747,021?

4. Are claims 1, 5-7, 9, and 25 unpatentable under 35 U.S.C. §102(b) as being anticipated by Sequeira et al. U.S. Patent No. 4,775,529?

5. Is claim 8 unpatentable under 35 U.S.C. §103(a) over Samour et al. U.S. Patent No. 5,976,566 in view of B.F. Goodrich Technical Disclosure entitled "Neutralizing Carbopol - - -," 1998?

VII. GROUPING OF CLAIMS

Applicants believe all of the pending claims, 1, 3, 5-9, 12 and 25 may be grouped together and will stand and fall together.

VIII. ARGUMENT

Initially, the Examiner rejects claims 1 and 6 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, the Examiner

asserts that the FDA guideline is not permanent, and therefore, the scope of the claims is uncertain. In addition, the Examiner asserts that the Applicants are incorporating essential matter into the application by reference. The Applicants/Appellants respectfully traverse this rejection. The FDA guideline is made permanent based upon the date of filing the application. One of skill in the art would readily understand and know what neutralizers are designated by the FDA as a direct food substance that is Generally Recognized As Safe on the date the application was filed. Those neutralizers will not change and cannot be changed, even if the FDA guideline is eventually changed.

Moreover, although Applicants/Appellants have attempted to amend the application and claims 1 and 6 to overcome this rejection by incorporating the subject matter the Examiner deemed essential into the specification and claims, Applicants/Appellants nevertheless traverse the rejection on the basis that the description of the neutralizers using the GRAS designation is nothing more than Applicants'/Appellants' attempt to set forth a clear, concise and definite designation already accepted by one department of the United States Government (i.e., the FDA) in a manner which would not require the listing of more than 80 different chemicals. Accordingly, the Applicants/Appellants respectfully request the Board to reconsider and withdraw the Examiner's rejection of claims 1 and 6 under 35 U.S.C. §112, second paragraph.

Next, the Examiner has rejected all of the pending claims except claim 8 as being anticipated by Samour et al. U.S. Patent No. 5,976,566. The Applicants/Appellants disagree with this rejection and note that Samour et al. is directed to formulation suitable for drug delivery through the skin using a penetration enhancer. In fact, the patent does not use the recited ethanol, carbomer polymer, and sodium hydroxide ingredients together in amounts and in a manner which would provide for an alcoholic gel composition suitable for use as a skin sanitizing composition. While all the ingredients may be recited somewhere in the patent, they are not used in the manner to suggest a sanitizing composition. Moreover, the additional parameters of the application, including the density and viscosity characteristics are not set forth in that

cited art reference and are not inherent therein, as has been proven by the testing set forth in Dr. Mojgan Cline's Declaration.

In fact, tests were done based upon the Samour et al. reference to try to obtain the compositions of the present invention. As noted in Dr. Mojgan Cline's Declaration, it was not possible to obtain such a composition. All of the compositions of Samour et al. became heavily clouded, and precipitation occurred. Thus, both compositions tested resulted in a zero viscosity solution with very heavy precipitation.

The Examiner, in her remarks in the Advisory Action, notes that Dr. Cline's Declaration was filed to support the superiority of the instant invention over those found in the cited patent art on the basis that Applicants' tests showed unsatisfactory end results with respect to viscosity and appearance. However, the Examiner asserts that Applicants have failed to include specific elements that make the claimed invention patentably distinct.

Applicants/Appellants respectfully disagree. The viscosity limitations are set forth clearly in claim 1 of the present invention. The Samour et al. reference, based upon testing of samples made pursuant to that patent, do not render or suggest a composition having sufficient viscosity as required of the antimicrobial skin sanitizing compositions of the present invention. The claims clearly define a patentable invention on the basis that the composition of Samour et al. falls outside the range of from about 1,000 to about 65,000 centipoise in viscosity. This is not a general allegation. It is clear that a product manufactured according to Samour et al. would not produce the sanitizing composition of the present invention, including the viscosity characteristics, and therefore, does not anticipate or render obvious the present invention.

Next, the Examiner has rejected all of the claims except claim 8 as being anticipated by McKenzie et al. U.S. Patent No. 5,747,021. Again, the Applicants/Appellants respectfully disagree with the Examiner's rejection for essentially the same reasons as set forth above for Samour et al. First, McKenzie et al. teaches an aftershave composition comprising water, glycerin, propylene glycol, carbomer, alcohols of various types, acetylsalicylic acid, Peg-8. Again, as supported by the Declaration of

Dr. Cline, the sample compositions prepared according to McKenzie et al. do not produce a viscous gel. Instead, as previously noted, sodium hydroxide did not succeed in getting the thickener, namely a carbomer polymer to gel to the desired viscosity where a larger amount (i.e., greater than 60%) of alcohol were used. Thus, it is believed quite clear that the present invention is patentable over the McKenzie et al. reference since the McKenzie et al. composition does not include a composition having a viscosity greater than 1,000 centipoise.

The sample composition prepared according to the McKenzie et al. reference, like Samour et al, does not produce a viscous gel. That is, the sodium hydroxide used in getting the thickener to gel is not sufficient for large alcoholic compositions. Accordingly, the present invention is believed patentable over McKenzie.

Next, the Examiner has rejected claims 1, 4-7, 9 and 25 as being anticipated by Sequeira et al. U.S. Patent No. 4,775,529. Again, the Applicants/Appellants disagree. As discussed with the Examiner, Sequeira et al. necessarily uses two types of alcohol (i.e., propylene glycol and isopropyl alcohol), while the present invention has now been limited to at least 60% by weight of just those aliphatic alcohols having 1 to 4 carbon atoms. Since Sequeira et al. teaches only 20 to 40% isopropyl alcohol, it does not meet the claims of the present invention. Accordingly, the present invention is believed patentable over the Sequeira et al. reference.

With respect to claim 8, the Applicants/Appellants rely on the novelty and nonobviousness of the parent claims(s) from which claim 8 depends for its novelty. Applicants/Appellants do not admit or acquiesce to the Examiner's rejection, but reserve the right to argue the patentability of this claim an its merits should the need arise.

In light of the foregoing, the Applicants respectfully request the Board to reverse the final Action, withdraw the rejections against the present application, and to issue a formal Notice of Allowance of claims 1, 3, 5-9, 12 and 25, the same being earnestly solicited. Should the Board or the Examiner care to discuss any of the foregoing, the undersigned attorney would welcome a telephone call.

Respectfully submitted,

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Attorney for Applicant(s)

Dated: August 24, 2004

APPENDIX

Claims 1, 3, 5-9, 12 and 25 on appeal as follows:

1. An antimicrobial skin sanitizing composition comprising:

at least about 60 weight percent of an aliphatic alcohol having from 1 to 4 carbon atoms selected from the group consisting of methanol, ethanol, propanol, isopropanol, butanol, isobutanol, and tertiary butanol;

from about 0.1 to about 5 weight percent of a thickening agent, wherein the thickening agent is a carbomer polymer; and

an effective amount of a neutralizer designated by the FDA as of February 5, 2002, as a direct food substance that is Generally Recognized As Safe or as an amino acid permitted for direct addition to food for human consumption, to neutralize the thickening agent, wherein the composition is not a mousse, has a density of at least 0.8 g/ml, and has a viscosity of from about 1,000 to about 65,000 centipoise at 70 degrees Fahrenheit.

3. The sanitizing composition of claim 1, wherein the alcohol is ethanol.

5. The sanitizing composition of claim 1, wherein the sanitizing composition comprises from about 60 to about 90 percent by weight alcohol.

6. The sanitizing composition of claim 1, wherein the neutralizer is designated by the FDA as of February 5, 2002 as Generally Recognized as Safe.

7. The sanitizing composition of claim 1, wherein the neutralizer contains a hydroxide selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, magnesium hydroxide, and precursors thereof.

8. The sanitizing composition of claim 1, wherein the neutralizer contains an amino acid selected from the group consisting arginine, cysteine, and thiamine.

9. The sanitizing composition of claim 7, wherein the neutralizer contains sodium hydroxide.

12. The sanitizing composition of claim 1, wherein the sanitizing composition further comprises one or more components selected from moisturizers, emollients, preservatives, perfumes, dyes, opacifiers, and lubricity agents.

25. An antimicrobial skin sanitizing composition comprising:

at least about 60 percent weight of an aliphatic alcohol having from 1 to 4 carbon atoms selected from the group consisting of methanol, ethanol, propanol, isopropanol, isopropanol, butanol, isobutanol, and tertiary butanol;

from about 0.1 to about 5 weight percent of a carbomer thickening agent; and

from about 0.0001 to about 0.2 weight percent sodium hydroxide to neutralize the thickening agent, wherein the composition is not a mousse, has a density of at least 0.8 g/ml, and has a viscosity of from about 1,000 to about 65,000 centipoise at 70 degrees Fahrenheit.